

§ 520.1443

(iii) *Limitations.* Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[55 FR 25301, June 21, 1990, as amended at 55 FR 49888, Dec. 3, 1990; 58 FR 5608, Jan. 22, 1993; 60 FR 50097, Sept. 28, 1995; 61 FR 43654, Aug. 26, 1996; 63 FR 29352, May 29, 1998; 63 FR 41189, Aug. 3, 1998. Redesignated at 77 FR 47512, Aug. 9, 2012]

§ 520.1443 Milbemycin oxime and lufenuron.

(a) *Specifications*—(1) Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use*—(A) For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult *Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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(2) [Reserved]

[62 FR 28629, May 27, 1997, as amended at 63 FR 41190, Aug. 3, 1998; 68 FR 51905, Aug. 29, 2003. Redesignated at 77 FR 47512, Aug. 9, 2012]

§ 520.1445 Milbemycin oxime and praziquantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime and 228 mg praziquantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer orally, once a month, a minimum dosage of 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)) milbemycin oxime and 2.28 mg/lb of body weight (5 mg/kg) praziquantel.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, and *E. granulosus*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[77 FR 47512, Aug. 9, 2012]

§ 520.1447 Milbemycin oxime, lufenuron, and praziquantel tablets.

(a) *Specifications.* Each tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime, 46 mg lufenuron, and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime, 115 mg lufenuron, and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime, 230 mg lufenuron, and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime, 460 mg lufenuron, and 228 mg praziquantel.